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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,178	10/28/2003	J. Daniel Raulerson	MED0065	4287

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EXAMINER	
VU, QUYNH-NHU HOANG	

ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
10/04/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@foxrothschild.com

Office Action Summary	Application No.	Applicant(s)	
	10/695,178	RAULERSON ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *34-40* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *34-40* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment and Request for Continued Examination (RCE) filed on 07/25/11 have been entered in the case. Claims 34-40 are pending for examination and claims 1-33 have been cancelled.

Claim Objections

Claim 34 is objected to because of the following informalities: a limitation "... the proximal end of the hub member" in line 19 should be changed --- a proximal end of the hub member ---. Appropriate correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation "the first and second catheters have transition sections between the first and second proximal end regions and the first and second intermediate sections" of claim 36 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

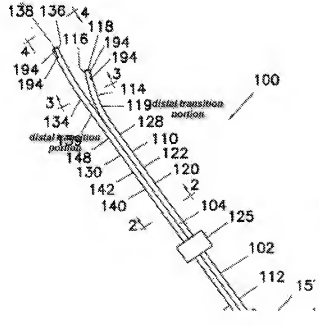
Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

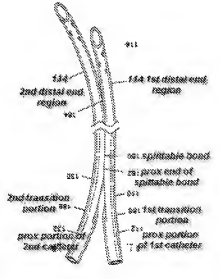
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 36 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the specification discloses that the limitation "the first and second catheters have transition sections between the first and second proximal end regions and the first and second intermediate sections." According to Figs 1 and 7 below, a first and second catheters have transition sections 119/139 (Fig. 1) or 186/188 (Fig. 7) between the first and second distal end regions and the first and second proximal portion.





According to para [0042] of Specification, the first transition portion 186 and second transition portion 188 are located in the very near proximity of the proximal end 182 of the splittable bond 180.

For examining purpose, Examiner will assume in two ways such as: 1st) a first and second catheters have transition sections between the first and second distal end regions and the first and

second proximal portion; or 2nd) the first transition portion and second transition portion are located in the very near proximity of the proximal end of the splittable bond.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 36 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant does not indicate a boundary of the first and second intermediate sections. Although one skill in the art would be understood the term "intermediate section" which is located in the middle section of proximal and distal sections, however, nowhere in the Specification discloses that the locations of first and second transition regions are located whether within intermediate sections or outside of intermediate sections. For example, as seen in Fig. 7, the transition portions 186/188 are located near or at proximal portion of 1st and 2nd catheters. Oppositely, Fig. 1 shows that the transition portions 119/138 are mostly located near or at distal end region of the 1st and 2nd catheters. Therefore, Examiner does not sure where is the exact location of intermediate section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 34-35, 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley et al. (US 4,405,313) in view of Consalvo (US 4,098,275) and either Raulerson (US 4,037,599) or Zia et al. (US 2002/0120224).

Regarding claim 34, Sisley discloses a multiple catheter assembly, comprising:

a first flexible catheter 12 having a first distal end region implantable into and along vasculature of a patient, and having a first proximal end region joined by a first intermediate section to the first distal end region;

a second flexible catheter 14 having a second distal end region implantable into and along vasculature of a patient, and having a second proximal end region joined by a second intermediate section to the second distal end region;

first and second extension tube assemblies (i.e. a catheter tube connected to fluid reservoir for infusion of medication and withdrawal of blood or other fluids from the patient and connected to the connectors 24 and 26, col. 5, lines 37- 41) having first and second distal end portions respectively associated with the first and second proximal end regions of the first and second catheters; and

a hub member 22 dimensioned and configured to be attachable by a practitioner directly to and around the first and second proximal end regions of the first and second catheters distally of the proximal ends thereof,

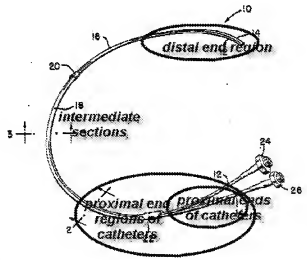
With regarding to the limitation "**after implantation** of the first and second distal end regions of the catheter and subcutaneous tunneling of the first and second proximal end regions of the catheter and at a site **selected by the practitioner along coextending", this is** a method step in device claim and it is considered as a functional limitation which only requires the capability of performing the claimed function and if the prior art structure(s) is/are capable of performing the claimed function then it (they) meet the claim language. In this case, Sisley discloses that the plastic, figure-8, dual-lumen catheter is inserted through the subcutaneous tunnel into the vessel, col. 2, lines 4-6. Therefore, the device of Sisley is capable of performing the step of after implantation of the first and second distal end regions of the catheter, see Fig. 4, and subcutaneous tunneling of the first and second proximal end regions (i.e. figure-8 region) of the catheter and at a site selected by the practitioner along coextending.

Sisley further discloses that separated lengths 12, 14 of the first and second proximal end regions spaced from the proximal ends thereof, such that portions of the proximal end regions of the first and second catheters extend through the hub member 22 and proximally beyond a proximal end of the hub member through respective exits and spaced apart from each other, and capable of or adapted to be

connecting/connected to respective ones of the first and second extension tube assemblies (i.e. connector 24, 26 connecting with first and second extension tube assemblies (i.e. connecting of catheter to reservoirs for infusion medication into or withdrawn blood), and other portions of the proximal end regions (i.e. at figure-8 portion located distally at distal portion of hub member 22) of the first and second catheters co-extend distally from the hub member separately from but adjacent to each other.

In case Applicant does not agree with Examiner that Sisley discloses a first and second extension tube assemblies, Consalvo discloses a multiple lumen catheter comprising: a first and second catheter; a hub member 14, a first and second extension tube assemblies 17, 18 having a first and second distal end portions respectively associated with a first and second proximal end regions 6, 12 of the first and second catheters.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Sisley with a first and second extension tube assemblies, as taught by Consalvo, in order to infusion a medication/liquid into a patient and withdrawn liquid/blood from a patient.



Sisley discloses that the hub member attached but can not be detached or separated to the catheter as required in claimed invention.

Zia discloses a hub device/tube holder 50 comprising: a first portion 51; a second portion 52; eyes 60; protrusion 61; wherein the eyes 60 provided in first mating portion will receive a pair of hooks/protrusion 61 provided on second portion, which will attached/fixedly and removably for a catheter.

In other the words, the operator can provide the hub device or tube holder 50 attached and detached to the catheter by opening (unhook protrusions 61 from eyes 60) or closing (hook protrusions 61 into eyes 60).

Alternatively, Raulerson teaches a hub device comprising: a hinge line such that folding of one hub portion relative to this hinge line into mating engagement with the other hub portion so that the hub member is opening and closed positions.

Giving such teaching by either Zia or Raulerson, a person having ordinary skill in the art would have easily recognizes that modifying the device of Sisley with providing an open/closed structure (i.e. protrusions, eyes and a hinge line) in a hub device, as taught by either Zia or Raulerson, would provide the benefit of adjustability (i.e. detachable or attachable) of the catheters in the support member in certain situations.

Regarding claim 35, either Sisley discloses that wherein the cross- sectional shapes of the first and second proximal end regions is circular, and the cross- sectional shapes of the first and second distal end portions of the first and second extension tubes is circular.

Regarding claims 39-40, a device of Sisley as modified by Consalvo and either Zia or Raulerson will bring the result such as the hub is attachable to the first and second catheters from beside them, and removable from around the first and second catheters the catheters, while the catheter distal end portions are implanted in a patient; wherein the hub is longitudinally translatable along the catheters after being attached thereto.

Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley et al. in view of Consalvo and either Raulerson or Zia et al. and further in view of Ash (US 5,947,953).

As best as understood, Sisley in view of Consalvo and either Zia or Raulerson discloses all claimed subject matter except for that the cross sectional shapes of the first and second intermediate sections of the first and second catheters is circular but not a semicircular, as requires in claim 36.

Ash discloses a similar catheter device comprising: the cross sectional shapes of the first and second intermediate sections of the first 26 and second catheters 30 is semicircular, see Fig. 4F; and the

first and second catheters have transition sections 48a' and 52a' between the first and second distal end region and first and second proximal portion; or with broadest interpretation, the transition section 48a' and 52a' are located near proximity of the proximal end of the proximal end of the splittable bond.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Sisley in view of Consalvo and either Zia or Raulerson with the semicircular cross sectional shapes of the first and second intermediate sections of the first and second catheter, as taught by Ash, in order to improve the blood flow rate in the catheter system.

Additionally, Applicant states that the beside the semicircular cross section shapes of catheter, other configurations may be used without departing from the spirit of the invention, such as, for example, oval, circular, elliptical, square...., see para [0032] of Specification. Therefore, one skill in the art would recognize that the circular cross section shape in Sisley can be modified in any shapes such as semicircular... is design choice.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sisley et al. in view of Consalvo and either Raulerson or Zia et al. and Ash and further in view of Cazal (US 5,800,414).

Sisley in view of Consalvo and Raulerson/Zia and Ash discloses the invention substantially as claimed. Sisley discloses that the 2 catheters 12 and 14 are attached by 18a, see Fig. 3. However, Sisley in view of Consalvo and Raulerson/Zia and Ash does not clearly mention that the catheters 12 and 14 are attached by adhesive.

Cazal discloses a similar device, in which the first and second catheters are splittably joined to each other by adhesive 14 or 20. It is noted that the adhesive 14 or 20 is capable of being splitted if using sufficient force to tear it.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Sisley in view of Consalvo and Raulerson/Zia and Ash, with an adhesive, as taught by Cazal, if one wished to easily join the two catheters.

Response to Arguments

Applicant's arguments with respect to claims 34-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Quynh-Nhu H. Vu/
Examiner, Art Unit 3763